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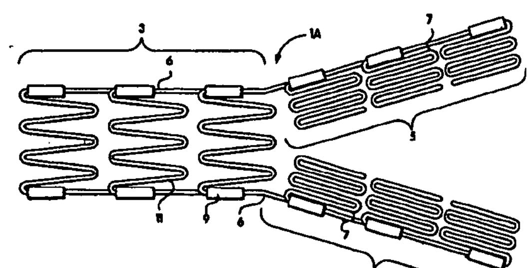
(54) Title: BIFURCATE STENT

(57) Abstract

An endoluminal stent is formed in a modular construction to include at least one elongate spine and plurality of general tube-defining modules attached to the spine, or spines, in a longitudinal array. The modules are constructed along a spine-like structure so as to form a bifurcate shape for implantation in branching or bifurcating vessels. Each module defines, in cooperation with a spine, a closed ring-like structure. Each of the modules is radially expandable from a reduced diameter, low profile configuration, in which it is readily navigated through the body passages, to an expanded diameter engageable with the inner luminal surface of the body lumen. The stent, being of modular construction, can be built to individual specifications for a specific patient. Modules are formed from a wire shaped in a flat serpentine configuration that is then wrapped in a cylindrical configuration with its free ends connected to a spine. The modules are expandable, as by a balloon, from a low profile to an expanded configuration. During expansion, the modules can wipe against the inner surface of the lumen to smooth sharp points or edges. A spine of the stent defines a substantially greater mass than that of the individual modules such that the spine can be readily observed under X-ray or fluoroscopy. The modular construction enables a wide rang of variation in the characteristics of the stent, including longitudinal flexibility, radial expansion characteristics, among others.



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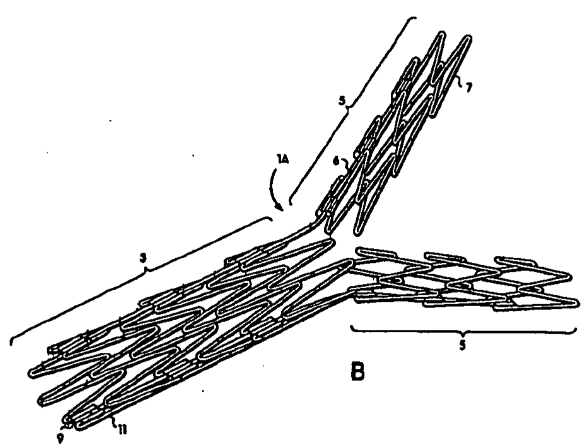

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BIFURCATE STENT

Background of the Invention

A number of medical procedures involve or can be supplemented with the placement of an endoluminal prostheses, commonly referred to as a stent, that can be implanted in a lumen, such as a blood vessel or other natural pathway of a patient's body. Such stents typically define a generally tubular configuration, and are expandable from a relatively small diameter (low profile) to an enlarged diameter. While in its low profile configuration, the stent is advanced endoluminally, by a delivery device, through the body lumen to the site where the stent is to be placed. The stent then can be expanded to a larger diameter to firmly engage the inner wall of the body lumen. When the stent is delivered satisfactorily the delivery device is removed, leaving the implanted stent in place. In that manner, the stent may serve to maintain open a blood vessel or other natural duct, the functioning of which had become impaired as a result of a pathological or traumatic occurrence.

Among the medical procedures in which stents have had increasing use is in connection with percutaneous transluminal angioplasty (PTA), and particularly percutaneous transluminal coronary angioplasty (PTCA). PTA and PTCA involve the insertion and manipulation of a dilating catheter through the patient's arteries to place the dilatation balloon of the catheter within an obstructed portion (stenosis) of a blood vessel. The balloon is expanded forcibly within the obstruction to dilate that portion of the blood vessel, thereby restoring blood flow through the blood vessel. Among the more significant complications that may result from such angioplasty is when the dilated site becomes

obstructed again, for example, by restenosis. By placing a stent within the blood vessel at the treated site, the tendency for such restenosis may be reduced.

Stenoses may often develop in the branching region of a patient's blood vessel. Treatment of a stenosis in the branched region may present numerous additional difficulties in the design of devices to dilate stenoses at the branched region. Techniques and devices have been developed to effect a dilatation at a branched region such as the "kissing balloon" technique described in U.S. patent 4,896,670, or pending Bard patent "Dual Balloon System." The need for an effective stent that can be placed at a bifurcated region has been recognized.

Summary of the Invention

The invention includes, *inter alia*, stents, methods for making stents, and procedures for treating restenosis and other conditions suitable for treatment by application of an endoluminal prosthesis. The stents described herein can include, but are not limited to, bifurcated stents constructed in a modular fashion and having at least one elongate spine suitable for disposition within a vessel. The spine can attach to a plurality of generally tubular modules to form a longitudinally sequenced array of such modules. Each module can define, in cooperation with its associated spine, a closed, ring-like structure, with the modules being aligned in an array to define a cage-like, generally tubular structure. Each of the modules may be formed from wire and is radially expandable from a reduced diameter, low profile configuration to an expanded diameter profile suitable for engaging with the inner luminal surface of a blood vessel or other body lumen. Each spine can include a longitudinal support wire to which the modules may be individually mounted in succession.

In one embodiment, the bifurcated stent is composed of three sections, one main body and two side branch sections. Each section can define a single tubular configuration having its own array of modules connected to and extending along at least one spine. The main body of the stent is connected to the two side branch sections by means of one or more spines and/or by means of the modules.

In one practice, the stents described herein can be placed onto a dual balloon catheter delivery system, or onto two balloon catheters and, while in the low profile configuration, can be advanced to a bifurcated vessel. A delivery system incorporating a protective retractable covering sleeve over the stent may also be employed. The stent can be deployed by applying a radial force to the modules, optionally by inflation of a balloon catheter.

Among the objectives of the invention is to provide an easily placable bifurcated endovascular stent.

Another object of the invention is to provide a bifurcated stent that can be placed in the coronary arteries as well as other branched vessels.

Another object of the invention is to provide a bifurcated stent that can be tailored to the vascular anatomy of the patient in whom the device is to be implanted.

Another object of the invention is to provide a bifurcated stent of which a region of the bifurcate stent, for example the region nearest the apex region of the branching vessel, can be independently tailored to suit the particular vessel.

A further object of the invention is to provide a bifurcated stent having good radiographic characteristics to facilitate placement and subsequent visualization of the stent.

Another object of the invention is to provide a bifurcated stent construction that is modular.

Another object of the invention is to provide a bifurcated stent that can be used as a scaffold for a PTFE, or other, graft for peripheral & coronary applications.

More particularly, the stents described herein include a bifurcated stent for placement in a body lumen having a main section and two side branch sections comprising of the plurality of individual modules connected to at least one support wire in the spine like configuration to form a tube-like structure that can be inserted to the body lumen in a low profile configuration which, by applying an outward radial force on the modules preferably by a balloon catheter, can be expanded to fit the body lumen.

The methods described herein include a method of deploying the stent, such as the above described bifurcated stent, wherein the stent is placed on a dual balloon catheter and is crimped down to its low profile configuration for insertion into the body lumen wherein it is positioned and deployed by the outward radial force exerted by the balloons. The method can include deploying the stent wherein the stent is placed on at least two balloon catheters and is crimped down to its low profile configuration for insertion into the body lumen where in its positioned and deployed by the outward radial force exerted by the balloons and the tube-defining members can be in elastically expanded.

The spines can be varied by offsetting the orientation of the spines relative to the bifurcation in order to tailor the stent to a particular bifurcated lumen, and number of spines utilized can vary in order to tailor the stent to a particular bifurcated lumen. The wall coverage of the stent can be increased or decreased and the wall coverage of a particular region of the stent can be increased or decreased to tailor the stent to a particular region or the stent can be increased or decreased to tailor the stent to a particular lumen,

for example by altering the shape of the wire used to create a module. Furthemore, the profile of the stent could be reduced by altering the profile of the connectors in at least one of the modules.

The spines of the stent can have substantially greater mass than the modules to enhance their radiographic visibility and the tube defining members can comprise at least one elongated spine having a plurality of modules connected to a spine(s) at sequential locations along the spine(s), each module defining a closed circumferential loop, the modules being arranged on the spine to define the tubular member and the modules being constructed to be expanded from a low profile configuration to an expanded configuration.

In one embodiment, each module is formed from a serpentine wire having a plurality of elongate segments alternate with shorter connective bends, the module being expandable by a balloon disposed within the tubular member such that when the balloon is expanded to cause expansion of the modules, the elongate segments of the modules will spread apart and wipe against the inner luminal surface of the lumen thereby to smooth the surface of the lumen.

In other emobdiments the spine defines a mass substantially greater than that of the modules sufficiently to present a radiographically visual image of the spine when the device is disposed in the body and when positioning the stent within the body lumen by reference to radiographic image of the spine. The bifurcated stent can include modules formed from a serpentine wire having a plurality of elongate segments alternate with shorter connective bends. The serpentine wire can have free terminal ends and is attached to the spine by a connector and the spine can comprise a longitudinal support wire and said connectors.

In another embodiment the bifurcated stent has at least one of the modules or support wires with a malleability different from the other. An in a further embodiment, there is at least one additional spine connected to at least some of the modules on at least one of the members and extending generally parallel to another spine. The modules, support wire and connectors can be formed from a material sufficiently similar in composition to inhibit development of corrosion at their respective junctures, such as a material belonging to the group comprising annealed stainless steel, titanium alloys, nickel gold alloys, nickel chromium alloys and titanium chromium alloys. Additionally, the stent can be coated with a protective material, such as carbon, or can be coated with a drug/drug eluting substance, such as an anticoagulant.

The stent can have an end modules attached to the support wire with the free terminal ends of one end module oriented toward the free terminal ends of the other end module. The modules can be inelastically deformable during expansion, and the stent can be dimensioned to be received in a human coronary artery while in a low profile configuration and to be expandable within the artery into engagement with the walls of the coronary artery. The stent can have a spacer disposed between adjacent connectors, the spacers being formed from the same material as the connectors, the spacers and connectors defining substantially continuous regions of high radipacity when visualized radiographically.

In one embodiement, the bifurcated stent has at least an elongated support wire formed from a non-metallic material, such as a polymeric material, nylon, or a bioabsorbable material.

In one embodiment the stent is protected by a retractable sleeve/sheath when positioning and can employ thinner radiopaque material to reduce the overall profile. The

device may be used as a scaffolding for a peripheral/coronary graft and an be positioned by a specific delivery system and which can facilitate expansion by some means afterwards, for example a separate balloon catheter.

Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following description thereof, with reference to the accompanying drawings wherein:

FIG. 1(a) is a side illustration of one bifurcate stent in a deployed configuration.

FIG. 1(b) provides an oblique perspective of one bifurcate stent in a deployed configuration.

FIG. 2 is a side illustration of one bifurcate stent in a deployed configuration with an alternative arrangement of spines in the side branches.

FIG. 3 is a side illustration of one bifurcate stent in a deployed configuration with a modified apex section to provide more wall coverage at the apex section of the branched vessel.

FIG. 4 is a diagrammatic illustration of a stent of the type depicted in Figs. 1-3 carried on two balloons while in a low profile configuration.

FIGs. 5(a)-(c) are diagrammatic illustrations of modules of the stent illustrating a possible connection to a support wire and some examples of different module configurations.

FIG. 6(a)-(c) illustrate, diagrammatically, one manner in which a bifurcate stent can be deployed using a dual balloon arrangement.

FIG. 7(a)-(e) illustrate, diagrammatically one technique for deploying a bifurcate stent by operation of separate balloon catheters.

Description of the Illustrative Embodiments

FIGs. 1(a)-(b) illustrate one type of modular endoprosthesis, a stent, that may be employed in practicing the invention. In particular, FIG. 1(a) depicts a stent having a main body 3 formed of modules 11 and connectors 9, and side branches 5 formed of side branch modules 7, and connectors 9. The depicted stent includes two spines 6, each of which extends substantially from the proximal end to the distal end of the stent. For clarity, the terms "proximal" and "distal" can be understood from the stent of FIG. 1(a) and from the definition that the main body 3 is proximal of the side branches 5. FIG 1(a) further depicts that each of the spines 6 extend along the sidewall of the main body 3, branching off at the apex formed where the side branches 5 join the main body 3. FIG 1(a) further depicts that each spines 6 attaches to a respective one of the side branches 5, and continues on distally, to provide a spine along the sidewall of the respective side branch 5. The spines 6 connect the main body 3 to each of the side branches 5. Optionally, one or more of the spines 6 can be formed from a flexible or resilient material, thereby allowing the side branches 5 to be brought together from the opened configuration of FIG. 1(a), to the closed configuration depicted in FIG. 4. Additionally, a resilient spring 6 can be biased in the open configuration of FIG. 1(a), such that the springs 6 will tend to move the stent from the closed configuration of FIG. 4, to the open configuration of FIG 1(a).

The endoprosthesis may be considered to define a cage-like tubular arrangement formed from wire-like components and having a main body section 3 and two side branch

sections 5. The stent depicted in FIGs. 1 (a)-(b) is constructed from a plurality of individual modules, containing main body modules 11 and side branch modules 7 connected to each other along at least one spine that may be considered to include a longitudinal support wire 6 and connectors 9. The modules 7 and 11 are expandable from a contracted, low profile configuration, to facilitate placement of the stent in the body lumen, to an enlarged diameter in which the modules can be brought into firm engagement with the inner surface of the walls of the body lumen to maintain the body lumen open to facilitate blood flow. In the one optional embodiment, the modules are expandable inelastically. The radially expandable generally tubular modules 7 and 11 are mounted and aligned in longitudinally sequenced array on the support wire 6 by a connector 9 associated with each of the modules 7 and 11. As detailed in FIG. 5(b), the modules 7, when mounted on a support wire 6, may be considered to define a virtual peripheral surface 12, that, in transverse cross-section, is in the form of a virtual closed curve or loop 8 about the longitudinal axis 2. Likewise the modules 11 in the main body 3, when mounted on at least one support wire 6, may also be considered to define a virtual peripheral surface.

Each module 7 and 11 can be formed from a wire 13 shaped and configured to enable radial expansion of the cylindrical peripheral surface 12. The module may be formed by first forming the wire 13 into a flat serpentine configuration and then wrapping the serpentine wire into its looped configuration. The terminal ends 16 of the serpentine wire 13 are free. The free ends 16 of the wire 13 may be attached to each other and to the support wire 6 by the connector 9. The serpentine arrangement of each of the modules may be considered to include a series of elongate segments alternated with and connected by bends that may be curved (e.g., circular) or may comprise shorter connective segments 15 connected to the elongate segments 14 at cusps 17. The connective bends between the

longitudinal segments 14 may lie along and define a locus of the closed loop 8. Preferably, the wire 13 is formed so that the arrangement of bends will be uniformly circumferentially spaced about the virtual closed loop 8 to provide the modules 7 and 11 with uniform strength in directions transverse to the support wire or wires 6.

As illustrated in FIG. 5(b) when the modules are in their low profile, unexpanded configuration, the bends 15, 17 that define the connection between adjacent longitudinal segments are such that the elongate segments 14 will lie substantially parallel to each other, defining an angle close to zero degrees. The angle will increase when the module is expanded, as shown in FIG. 5(a). The configuration of the connective bends, including the cusps 17 may be varied to vary the angle or to vary their number circumferentially about the closed loop 8 to vary the characteristics of the modules 7 and 11, including varying its resistance to compressive radial loads such that the endoprosthesis can further be tailored and made to conform ideally to the specific body lumen in which it is to be implanted.

By way of illustrative example only, a stent may be provided to include modules 7 formed from wire having a diameter of about 0.15 millimeter with elongate segments 14 (not including the connective bends between adjacent segments 14) of a length of about 1.8 millimeters. When the connective bends between adjacent elongate segments 14 are smoothly curved, they may have a radius of about 0.15 millimeter before expansion. A stent having the foregoing dimensions can be expected to be expandable to diameters between about 2.5 to about 4.0 millimeters without excessive expansion, and that such stent exhibits substantial resistance to radial collapse that can be well above the maximum radial compressive loads and can be expected to be imposed on the stent by contraction of an artery having a luminal diameter of about 2.5 to about 4.0 millimeters.

Again by way of illustrative example only, a stent may be provided to include modules 11 formed from wire having a diameter of about 0.15 millimeter with elongate segments 14 (not including the connective bends between adjacent segments 14) of a length of about 2.7 millimeters. When the connective bends between adjacent elongate segments 14 are smoothly curved, they may have a radius of about 0.15 millimeter before expansion. A stent having the foregoing dimensions can be expected to be expandable to diameters between about 3.0 to about 5.5 millimeters without excessive expansion, and that such stent exhibits substantial resistance to radial collapse that is well above the maximum radial compressive loads and can be expected to be imposed on the stent by contraction of an artery having a luminal diameter of about 3.0 to about 5.5 millimeters.

In one embodiment, the connectors 9 may be constructed to be mounted on the longitudinal support wire 6 as by threading them on the wire 6. The connector 9 preferably may comprise a ring that defines sufficient internal space to receive and circumscribe the free ends 16 of the wire 13 while also permitting firm connection of the ring to the longitudinal support wire 6. The ring connection 9, free ends 16 of the wire and support wire 6 may be firmly connected by means of a permanent deformation, for example, by crimping, or may be attached to each other by spot welding. When assembled using laser spot welding, it is preferred that the terminal portions 16 of the module 7 or 11 are first welded to the ring(s) 9 and the ring(s) 9 then is welded to the support wire 6. In some instances, it may be desirable to modify the stent so that one or more of the modules (but typically not the endmost modules) are not securely attached to the support wire but, instead, are permitted some freedom of sliding movement along the support wire. This may enable making of a final adjustment to the position of the module after the device has been placed in the patient's blood vessel, should that be desired.

A ring 9 may be in the form of a relatively short segment of a tube receptive to the support wire 6 and the free ends 16 of the modules 7 and 11. The internal surface of the ring 9 may be contoured to closely match the contour defined by the support wire 6 and free ends 16 that pass through the connectors 9, thus in effect preforming the ring.

The foregoing construction enables a stent to be specially assembled to conform precisely to the specific anatomy of the patient in whom the stent is to be placed. The modules can be positioned as desired along the support wire 6 and can be secured in that configuration. The support wire 6 may be selected to provide the desired degree of longitudinal flexibility and may be made from wire that is extremely flexible to aid in each of positioning of the device. With the foregoing construction in which the stent has at least one independent support wire 6 in each section, the degree of stiffness or flexibility of the support wire can be selected independently of the wire from which the tubular modules 7 are formed. The support wire 6 may be highly flexible to aid the stent to be carried through tortuous vessels, such ad coronary arteries.

It should be understood that although the presently preferred embodiment of the invention incorporates a metal support wire 6 (e.g., stainless steel), the modular construction of the invention enables a fabrication of a stent in which the support wire may be formed from non-metallic materials, such a polymeric materials, for example, nylon. Other mechanically and biologically suitable classes of materials may be selected, including materials from among those that are biologically absorbable into the tissue of the vessel wall over time. With a bioabsorbable support wire 6, it should be selected to maintain its desirable mechanical characteristics for a sufficient time to enable the modules 7 to become firmly embedded in the vessel wall. Thus, the modular construction of the invention

provides a substantially increased range of materials and properties for the individual components, each being selected to provide optimum results.

The connecting rings 9, especially when assembled about the two end segments 16 of the modules 7 and 11 and the support wire 6, present a significantly greater mass than that of the wire 13 from which the modules are fashioned. Thus, the region of the spine that includes the connecting rings 9 will present substantially greater radiopacity than that presented by the wire 13 of the associated module. The substantially increased radiopacity of the connected region enhances substantially the radiographic control of the endoprosthesis 1(a)-(c) during implantation. It also enables the prosthesis to be observed radiographically at a later time without requiring use of ultrasound procedures. The configuration of the stent enables the tubular frame 10 to be constructed to have a high mechanical strength while enabling expansion of the device between its low profile and maximum expanded alloys, and titanium-chromium alloys.

The support wire 6 and modules may be treated and formed to vary the mechanical and functional characteristics independently of each other to obtain a desired configuration adapted to treat the anatomy of a specific patient. For example, the wire 13 from which the module is formed may be subjected to an annealing heat treatment to control the malleability of the wire.

Also among the characteristics of the invention is the manner in which the tubular modules 7 protect the balloon of a balloon catheter 4 (FIG. 4) used in the placement of the endoprosthesis 1(a)-(c). When the device if mounted on the folded balloon of the catheter and is in its low profile phase adapted for delivery, the elongate segments 14 will be disposed in close. substantially parallel proximity to each other circumferentially about the

balloon. Additionally, to the extent ta that the individual tubular modules can be arranged in close longitudinal proximity to each other the balloon can be fully protected within the stent longitudinally as well as circumferentially. After the device and catheter 4 have been navigated to locate the deployment site, expansion of the device can cause the elongate segments 14 to spread and expand circumferentially along the walls to the body lumen to wipe against the walls and smooth surface roughness that may be present including, particularly, smoothing of sharp or hard regions that otherwise could damage the balloon and possibly result in balloon puncture. As the segments 14 of the module wipe against the walls of the passage, they effect a significant shearing action.

It may be noted that the main body 3 and side branch 5 sections may be constructed with multiple spines. FIG.5(c) illustrates an arrangement in which the module is constructed using two connectors 9 and support wires 6 circumferentially spaced about the virtual periphery 12, so as to create two spines. In this embodiment, each of the wires 13 of the modules 11 is formed to circumscribe about 180° of the loop defined by the module such that they can cooperate to define the generally cylindrical configuration. The connectors 9 shown in FIG. 5(c) may be pre-formed into a shape as shown so as to aid placement of the wire 13 during manufacture.

FIG. 6 illustrates a possible technique to deploy the stent, shown here as a general outline 24 to simply the diagram and aid viewing, using a balloon arrangement. Two guide wires 19 are positioned in the bifurcate vessel 18 by means of the known prior art. This is illustrated in FIG. 6(a). The bifurcate stent is crimped into the dual balloons to obtain the low profile state and the two balloons of the dual balloon catheter with the crimped stent are advanced over the guide wires to the bifurcate vessel as depicted in FIG. 6(b). The system can be advanced through a guiding catheter (not shown) to the site of the bifurcated

vessel by any suitable system or method known in the art. The dual balloon catheter is now used to expand the stent to its deployed configuration by applying a radial force on the modules of the stent by means of the two balloons 25, as depicted in FIG. 6(c). The balloons 25 are now deflated and can be removed along with the guide wires 19 to leave the stent 24 in its deployed configuration.

FIG. 7 illustrates one possible technique to deploy the stent, again shown here as a general outline 24 to simplify the diagram and aid viewing, using standard balloon catheters. Two guide wires 19 are positioned in the bifurcate vessel 18 by any means known in the art. The stent is crimped down onto two separate balloons, one balloon 21, being longer than the other 22. The bifurcate stent is crimped onto the two balloons 21 and 22 to obtain the low profile state and the two balloons 21 and 22 with the crimped stent are advanced over the guide wires to the bifurcate vessel 18 as depicted in FIG 7(a). The system can be advanced through a guiding catheter to the site of the bifurcated vessel by any suitable system or method known in the art. The two balloon catheters is now used to expand the stent 24 to its deployed configuration by applying a radial force on the modules of the stent 24 to its deployed configuration by applying a radial force on the modules of the stent 24 by means of the two balloons 21 and 22 sized to fit the side branch vessels 28. as depicted in FIG. 7(b). The balloons 21 and 22 are now deflated and can be removed. A third balloon 23, sized to fit the main branch vessel 27 can now be inserted over one of the guide wires 19, as shown in FIG. 7(d). The balloon 23 can now be deflated and can be removed along with the guide wires 19 to leave the stent 24 in its deployed configuration, as shown in FIG. 7(e).

If desired, the wires embodied in the stent 1(a)-(c) may be coated with a protective material such as carbon or with an anticoagulant substance such as heparin.

In a further alternative embodiment, the stent may be expandable by other means, for example, by forming the module 7 from a shape memory alloy such as nitinol. The stent may be provided with electrical resistance heaters to generate sufficient heat to induce thermally controlled expansion of the shape memory alloy module. A delivery system could be used to position the stent in the bifurcated vessel which would facilitate expansion of the stent after placement.

If felt necessary after deployment, post dilatation with balloons tailored to the artery could follow the stent deployment.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other embodiments, modifications and equivalents will be apparent to those skilled in the art without departing from its principles.

Claims

1. A bifurcated stent for placement in a body lumen having a main section and two side branch sections comprising of the plurality of individual modules connected to at least one support wire in the spine like configuration to form a tube-like structure that can be inserted to the body lumen in a low profile configuration which, by applying an outward radial force on the modules preferably by a balloon catheter, can be expanded to fit the body lumen.

2. A method of deploying the stent, as defined in claim 1, wherein the stent is placed on a dual balloon catheter and is crimped down to its low profile configuration for insertion into the body lumen wherein it is positioned and deployed by the outward radial force exerted by the balloons.

3. A method of deploying the stent as defined in claim 1 wherein the stent is placed on at least two balloon catheters and is crimped down to its low profile configuration for insertion into the body lumen where in its positioned and deployed by the outward radial force exerted by the balloons.

4. A method as defined in each of the preceding claims wherein the tube-defining members are in elastically expanded.

5. A method by which the configuration of the spines can be varied by offsetting the orientation of the spines relative to the bifurcation in order to tailor the stent to a particular bifurcated lumen.

6. A method by which the number of spines utilized is varied in order to tailor the stent to a particular bifurcated lumen.

7. A method by which the wall coverage of the stent can be increased or decreased.

8. A method by which the wall coverage of a particular region of the stent can be increased or decreased to tailor the stent to a particular region of the stent can be increased or decreased to tailor the stent to a particular lumen, for example by altering the shape of the wire used to create a module.

9. A method by which the profile of the stent could be reduced by altering the profile of the connectors in at least one of the modules.

10. A method as defined in claim 1 wherein the spines have substantially greater mass than the modules to enhance their radiographic visibility.

11. A method as defined in claim 1 wherein the tube defining members comprise at least one elongated spine:

a plurality of modules connected to a spine(s) at sequential locations along the spine(s), each module defining a closed circumferential loop, the modules being arranged on the spine to define the tubular member:

the modular being constructed to be expanded from a low profile configuration to an expanded configuration.

12. A method as defined in claim 11 wherein each module is formed from a serpentine wire having a plurality of elongate segments alternate with shorter connective bends, the module being expandable by a balloon disposed within the tubular member such that when the balloon is expanded to cause expansion of the modules, the elongate segments of the modules will spread apart and wipe against the inner luminal surface of the lumen thereby to smooth the surface of the lumen.

13. A method as defined in claim 12 wherein the spine defines a mass substantially greater than that of the modules sufficiently to present a radiographically

visual image of the spine when the device is disposed in the body and when positioning the stent within the body lumen by reference to radiographic image of the spine.

14. A bifurcated stent comprising as defined in claim 1 wherein each module is formed from a serpentine wire having a plurality of elongate segments alternate with shorter connective bends.

15. An endoprosthesis and defined in claim 1 wherein the serpentine wire has free terminal ends and is attached to the spine by a connector.

16. A bifurcated stent as defined in claim 15 wherein the spine comprises a longitudinal support wire and said connectors.

17. A bifurcated stent as defined in claim 16 wherein at least one of the modules or support wire has a malleability different from the other.

18. A stent as defined in claim 1 further comprising at lease one additional spine connected to at least some of the modules on at least one of the members and extending generally parallel to another spine.

19. A stent as defined in claim 15 wherein each of the modules, support wire and connectors are formed from a material sufficiently similar in composition to inhibit development of corrosion at their respective junctures.

20. A stent as defined in claim 15 wherein the modules are formed from a material belonging to the group comprising annealed stainless steel, titanium alloys, nickel gold alloys, nickel chromium alloys and titanium chromium alloys.

21. A stent as defined in claim 15 wherein the stent is coated with a protective material.

22. A stent as defined in claim 15 wherein the protective material comprises carbon.

23. A stent a defined in claim 15 herein a endoprosthesis is coated with a drug/drug elating substance.

24. An endoprosthesis as defined in claim 23 wherein the drug comprises an anticoagulant.

25. A stent as defined in claim 15 wherein the end modules of the stent are attached to the support wire with the free terminal ends of one end module oriented toward the free terminal ends of the other end module.

26. A bifurcated stent as defined in claim 1 herein the modules are inelastically deformable during expansion.

27. A bifurcated stent as defined in claim 15 with dimensions to be receivable in a human coronary artery while in a low profile configuration and to be expandable within the artery into engagement with the walls of the coronary artery.

28. A bifurcated stent as defined in claim 16 further comprising a spacer disposed between adjacent connectors, the spacers being formed from the same material as the connectors, the spacers and connectors defining substantially continuous regions of high radipacity when visualized radiographically.

29. A bifurcated stent as defined in claim 16 wherein at least the elongated support wire is formed from a non-metallic material.

30. An endoprosthesis as defined in claim 29 wherein the non-metallic material comprises a polymeric material.

31. An endoprosthesis as defined in claim 30 wherein the material comprises nylon.

32. An endoprosthesis as defined in claim 31 wherein the material for the elongated support wire comprises a bioabsorbable material.

33. A method of deploying stent claim 1 whereby the stent is protected by a retractable sleeve/sheath when positioning.

34. A method of deploying the stent, defined in claim 1, is made of thinner radiopaque material to reduce the overall profile.

35. A method as described in claim 1 by which the device may be used as a scaffolding for a peripheral/coronary graft.

36. A method by which the stent in claim 1 can be positioned by a specific delivery system and which can facilitate expansion by some means afterwards, for example a separate balloon catheter.

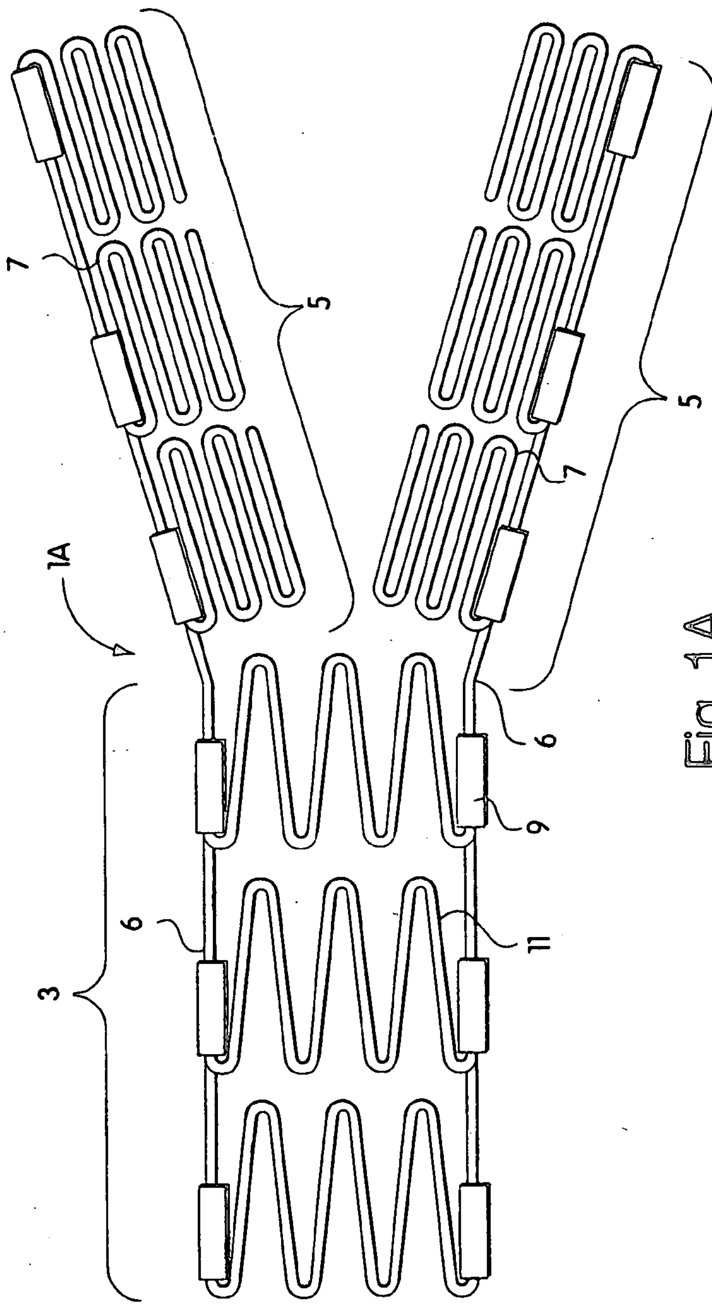

Fig. 1A

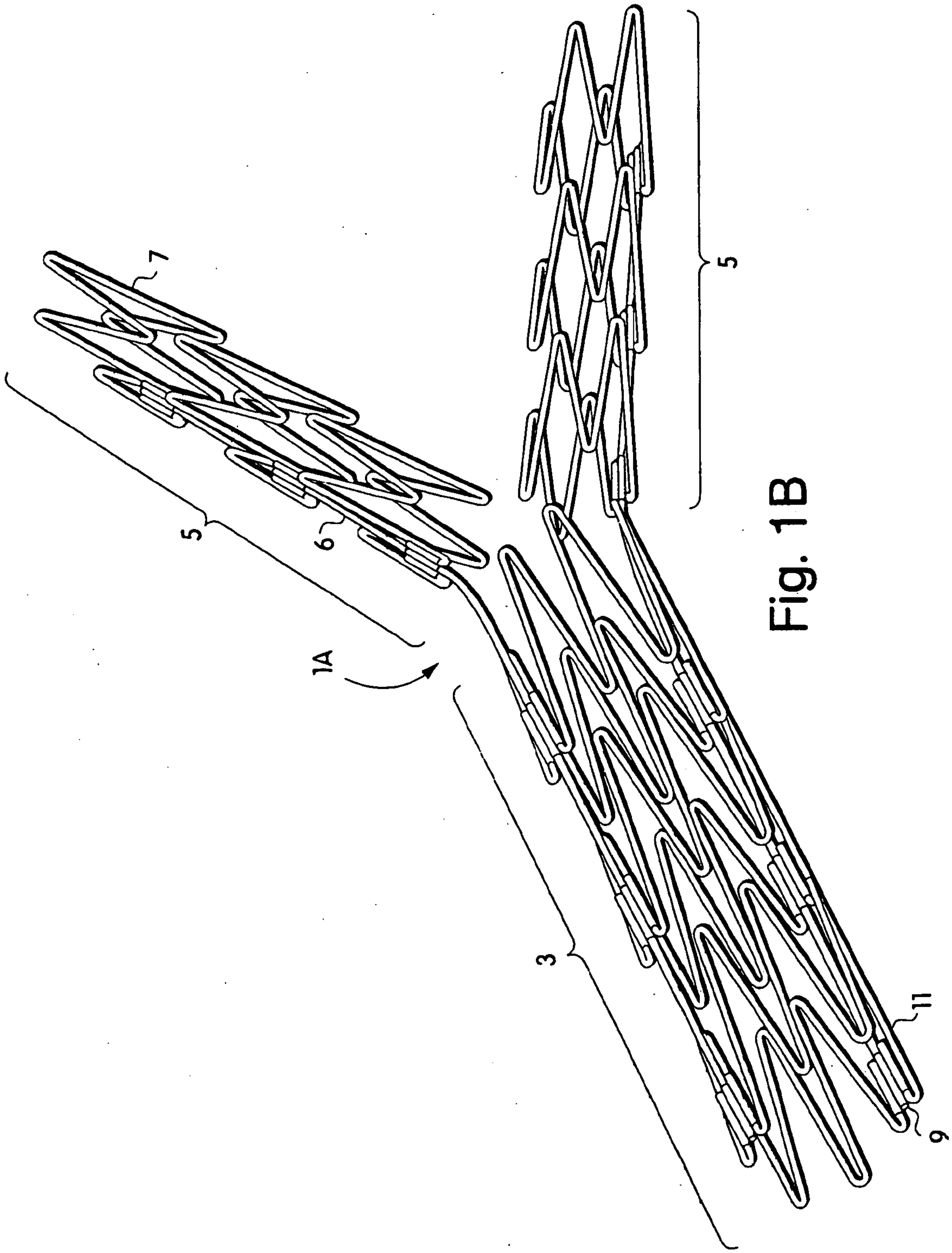

Fig. 1B

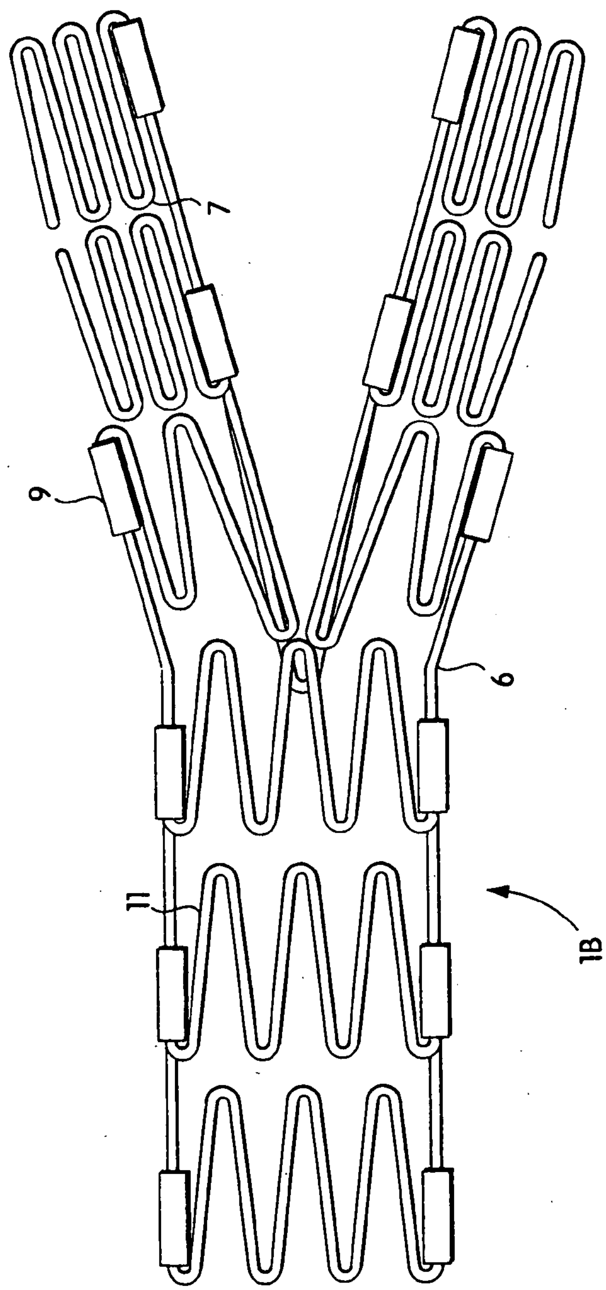

Fig. 2

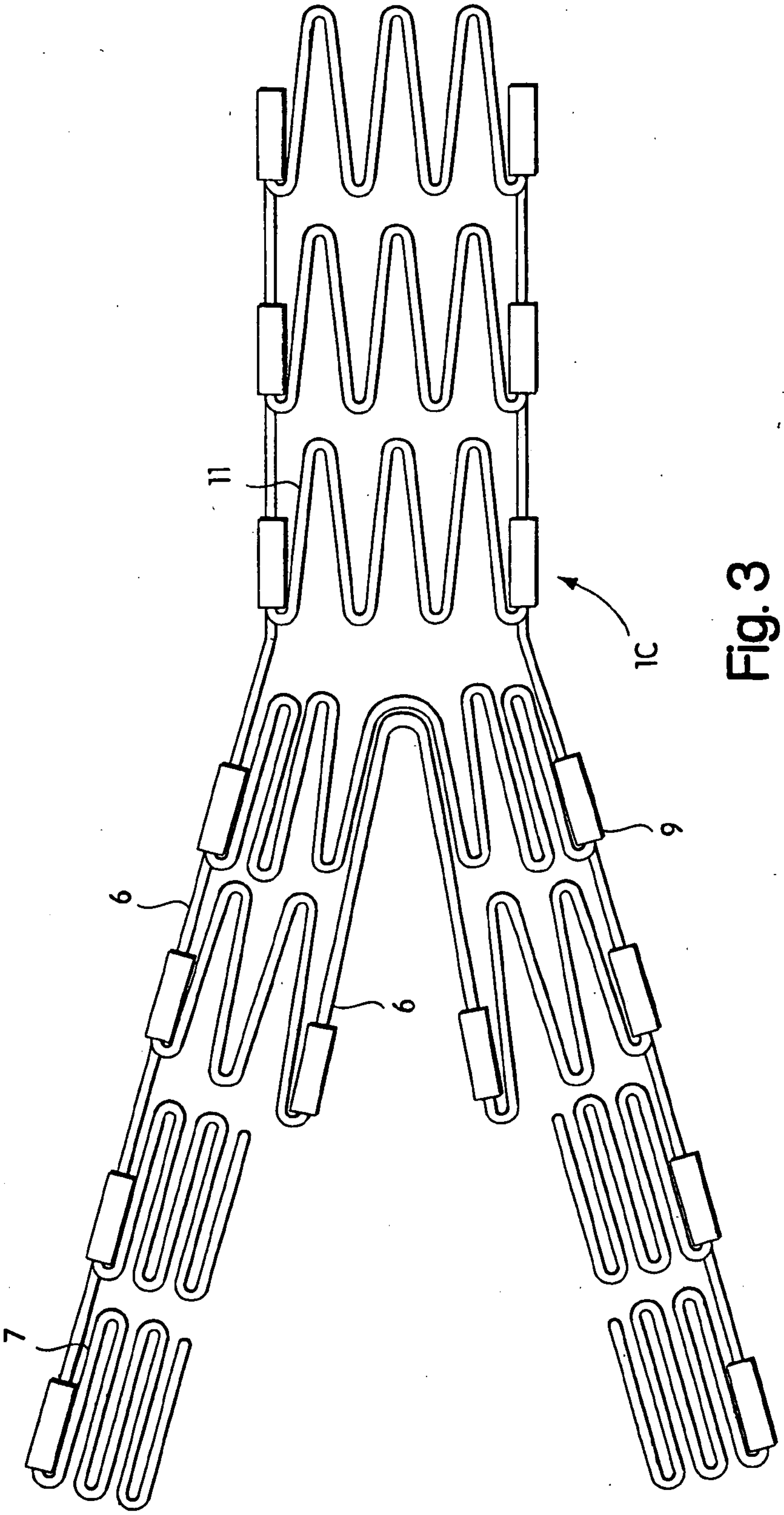

Fig. 3

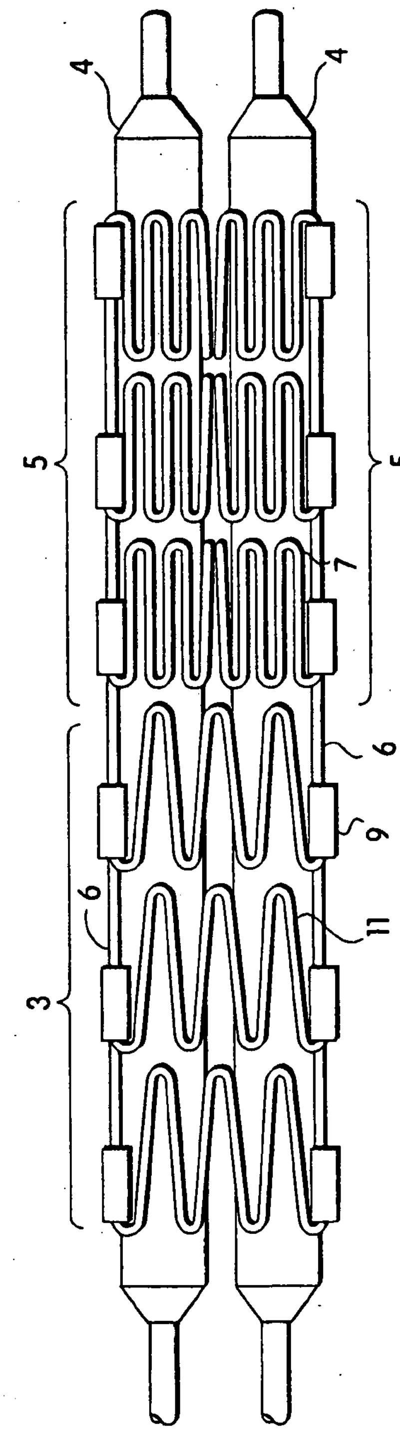

Fig. 4

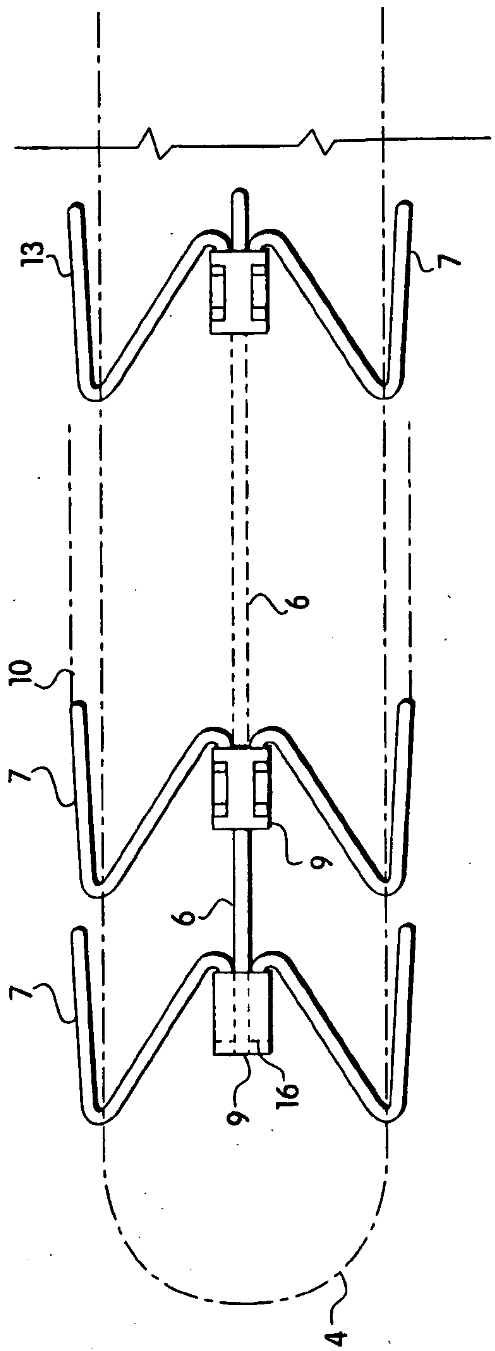

Fig. 5A

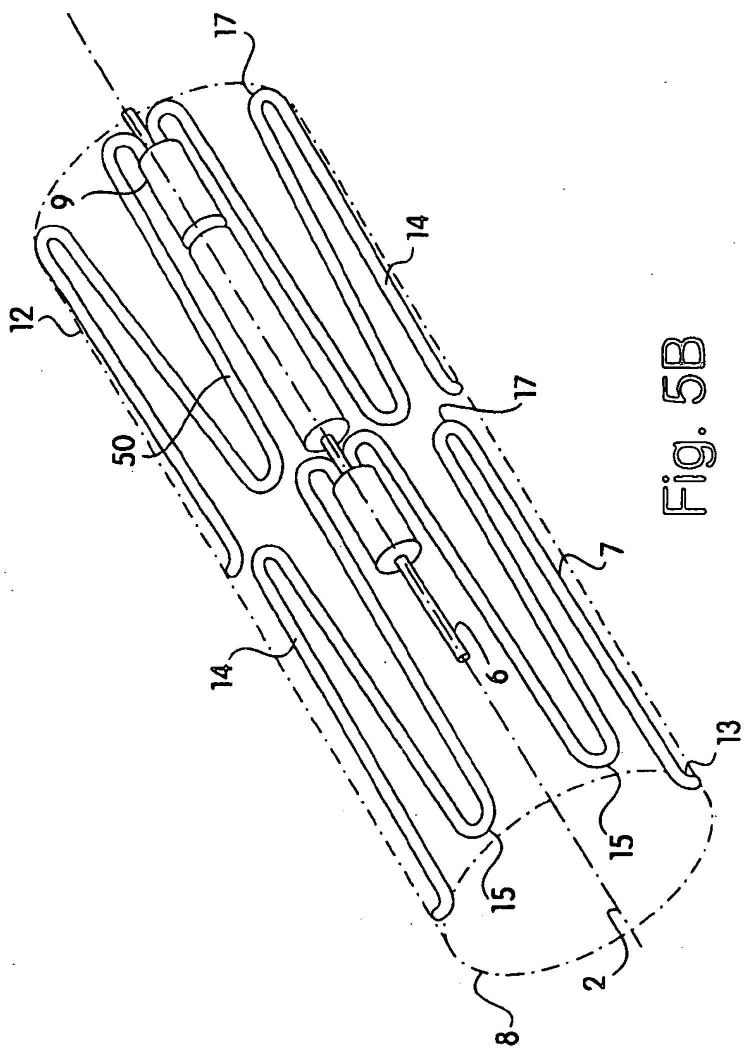

Fig. 5B

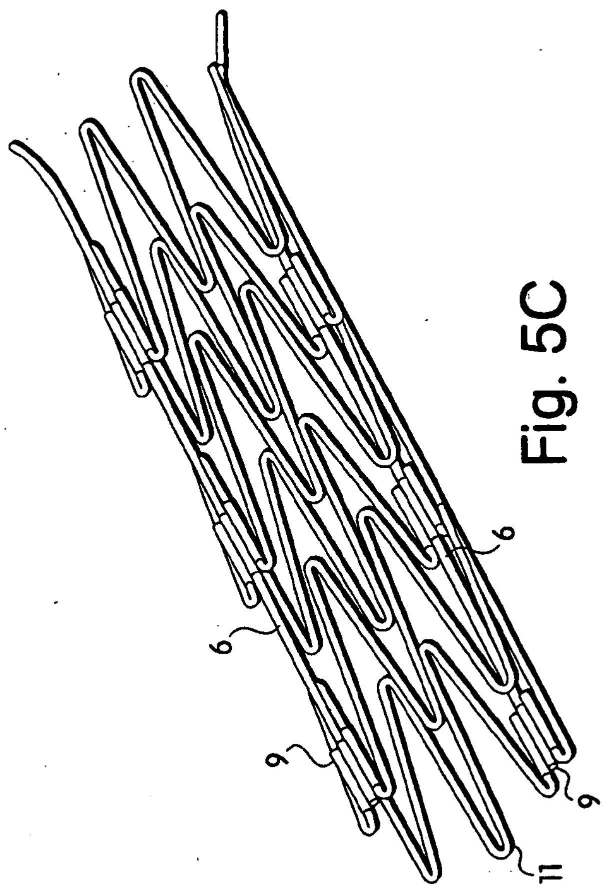

Fig. 5C

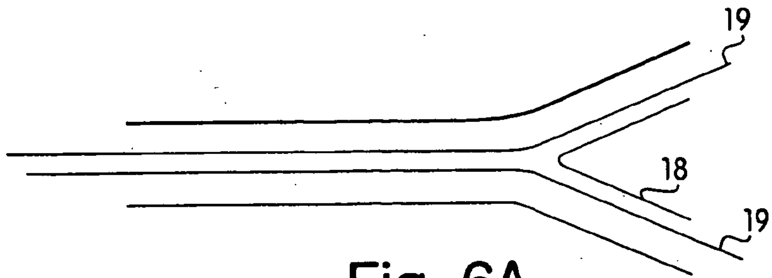

Fig. 6A

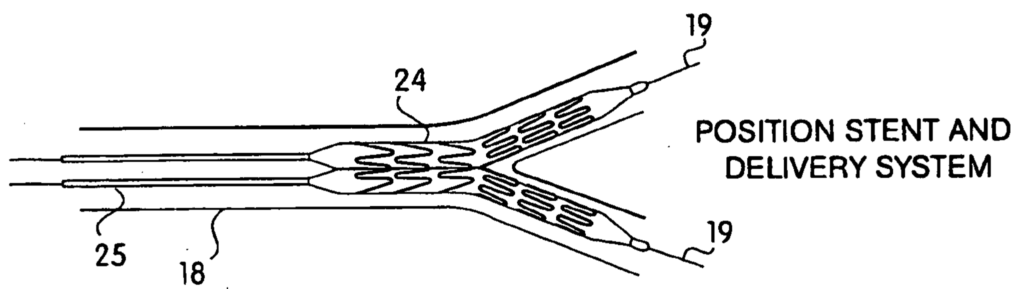

Fig. 6B

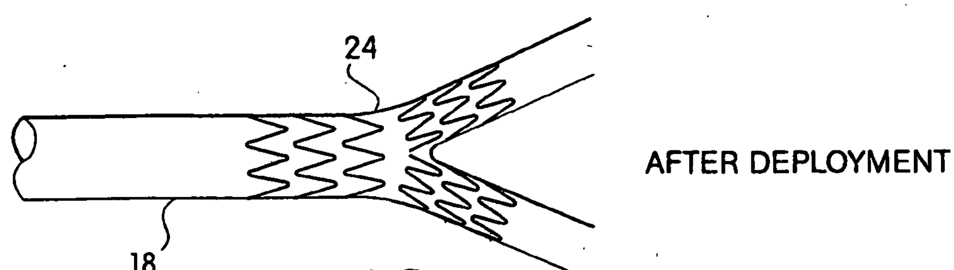

Fig. 6C

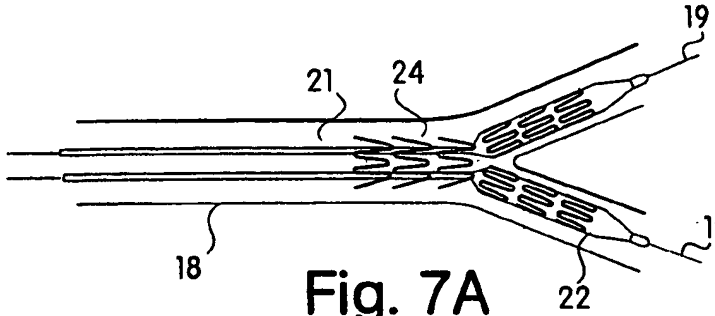

Fig. 7A

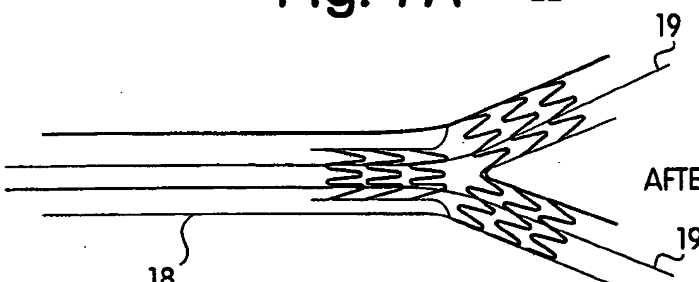

Fig. 7B

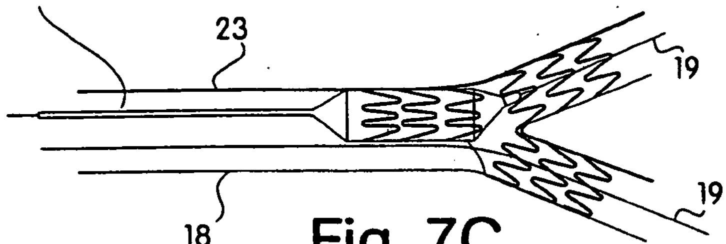

Fig. 7C

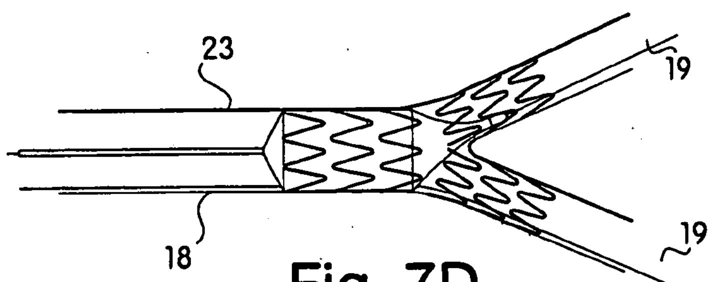

Fig. 7D

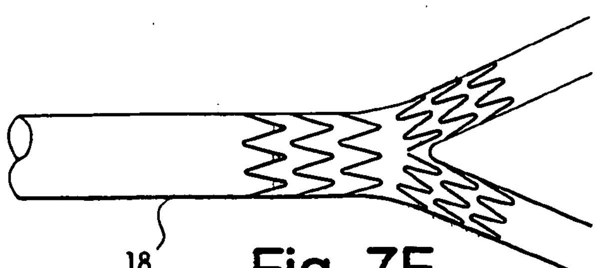

Fig. 7E